

REMARKS

In the Office Action, claims 4, 5 and 8 were indicated as being indefinite for depending from claim 20. In order to expedite prosecution, claims 4, 5 and 8 have been renumbered as new claims 31-33. The claims still depend from claim 20. In no way has the scope of claims 4, 5 and 8 been narrowed by this Amendment.

In the Office Action, the pending claims were also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,228,605. Please note that although one of the inventors of the present application is also the listed inventor on the '605 patent, the '605 patent and the present application are not owned by the same entity. Thus, Applicants believe that the '605 patent may not be used to substantiate an obviousness-type double patenting rejection. Further, due to the differences between the subject matter disclosed and claimed in the '605 patent and the presently pending claims, Applicants also hereby respond as follows.

As stated in the specification, the present invention is generally directed to a material for detecting the presence urease in a gastric material for diagnosing a gastrointestinal disorder. The material is in powder form and contains urea in a finely powdered, dry state. As stated on page 6, by maintaining urea in a powdered form separate from liquid or gel-like ingredients, such as indicators and agar, the urea remains more stable. Thus, the material need not be refrigerated and has a much longer shelf life than many prior art systems.

In one embodiment, as described in the specification, in order to detect a gastrointestinal disorder, a biopsy sample is obtained from the lining of the gastrointestinal tract of a patient. The biopsy sample is contacted with the powdered urea. The sample is then contacted with an indicator to indicate the presence of urease. A positive test for urease indicates a possible gastrointestinal disorder.

In an alternative embodiment of the present invention, the indicator and the urea may be combined together if the indicator is in a dry form. In this embodiment, the biopsy sample is contacted with a single composition testing the presence of urease.

In U.S. Patent No. 6,228,605, on the other hand, a method for the in vivo detection of urease-producing *Helicobacter* in the upper stomach is disclosed. A dense

carrier is used which is divided into two separate groups. The first group is combined with a first reagent indicator and the second group is combined with a second reagent indicator and urea. The two groups of the dense carrier are then ingested by a patient. The indicators are used to detect a pH change during endoscopy to indicate the possible presence of H.pylori.

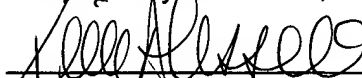
Applicants submit that the currently pending claims of the present application directed to a material and directed to a product are patentably distinct from claims 1-15 of the '605 patent which are all directed to a method of detecting, in vivo, a presence or absence of urease producing Helicobacter in a patient's stomach. Further, the '605 patent does not disclose or claim a powder containing urea and an indicator wherein the urea has a mean particle size of less than about 0.1mm as required in claim 1; does not disclose or claim a powder containing urea and an anti-caking agent as required in claims 10 and 18; does not disclose or claim a powder containing urea and a bactericide as required in claim 21; and does not disclose or claim a product comprising a container defining a well in which the well contains a composition containing urea and an anti-caking agent. As such, Applicants submit that the presently pending claims patentably define over the '605 patent whether based upon a double patenting rejection or a rejection under 35 U.S.C. § 102(e).

As now amended, all of the claims should be in complete condition for allowance. Favorable action, therefore, is respectfully requested. Should any issues remain after consideration of this response, however, then Examiner Leary is invited and encouraged to telephone the undersigned at her convenience.

1/16/04

Date

Respectfully submitted,



Timothy A. Cassidy
DORITY & MANNING, P.A.

P.O. Box 1449
Greenville, SC 29602
(864) 271-1592
(864) 233-7342